

II. REMARKS/ARGUMENTS

A. Status of the Claims

Claims 1, 3-16, 18-34 were pending when the September 4, 2008 Office Action was mailed to the Applicants. All of the pending claims were rejected by the Action. Claim 1 has been amended. No new matter was introduced. No new claims have been added; therefore, claims 1, 3-16 and 18-34 are currently pending and are presented for reconsideration.

B. The Anticipation Rejection Is Overcome

The Action has reintroduced a previous rejection, arguing that the pending claims are anticipated by Biegajski *et al.* As noted in the Action, during the Interview of May 15, 2008, Examiner Azpuru and Applicants' Attorney, Mark Voges, agreed that Biegajski *et al.* does not read on claim 1, or any of the other claims pending at that time. In revisiting this issue, Examiner Azpuru raises the concern that claim 1 might be broadly construed to read on the laminates and adhesive films disclosed by Biegajski *et al.* Applicants disagree for the following reasons.

First Applicants note that claims 1 and 16, as well as all their dependent claims, are limited by their preambles to gels. According to the MPEP, "Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation." MPEP § 2111.02. Since gel is a structural term, as opposed to a functional term, it follows that it must be treated as a claim limitation.

Second, for a gel to cover the types of laminates disclosed by Biegajski *et al.*, the term gel would need to be interpreted more broadly than the Application allows. The Specification defines the term gel as follows:

“A gel is defined as a semisolid consisting of particles interpenetrated by a liquid.”

Specification at page 17 (last two lines). This definition excludes the two-part adhesive and backing layer described in the portion of Biegajski *et al.* (col. 33, lines 55-60) cited by the Action. The backing layers are clearly not particles or particles interpenetrated by a liquid, nor do they become particles or particles interpenetrated by a liquid when they are combined with an adhesive. So while the above portion of Biegajski *et al.* does mention substances that are poorly soluble in water, Biegajski *et al.* isn't teaching or suggesting using these substances as ingredients in a pharmaceutical gel. Instead, these materials are provided as examples of materials suitable for backing layers that can be used to cover adhesives.

Third, the use of the open-ended language “comprising” in claims 1 and 16 does not enlarge or affect the definition of gel, which is itself already defined using close-ended “consisting of” language. That is Applicants concede that “comprising” is open-ended; however, it is not so open ended that the claim could cover something other than a gel. Stated another way, the term gel remains a claim limitation and the word “comprising” does not change that. Furthermore, Applicants note that the definition of gel in the Specification already employs the phrase “consisting of”—the very phrase suggested by the Examiner (Action at page 4). Since the claims use the term gel, and since gel is defined as it is above, the phrase “consisting of” is already a part of the pending claims. As such, Applicants believe that the Examiner's concerns are misplaced and/or have already been addressed by the currently pending claims.

For the above reason, as well as the reasons presented in Response filed May 20, 2008, Applicants maintain that Biegajski *et al.* fails to disclose or suggest at least one element of Applicants' claimed pharmaceutical gel, namely “water-insoluble swellable mucoadhesive

polymer” **particles**. Therefore, Applicants request that the current anticipation rejection be withdrawn as to claims 1 and 16. Furthermore, since all the other pending claims are dependent on either claim 1 or 16, Applicants also respectfully request that the corresponding rejections to these claims also be withdrawn. Applicants reserve the right to raise additional arguments regarding the patentability of these dependent claims, if needed.

C. Conclusion

It is believed that no fees are required in connection with the filing of this document. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the filing of this document, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/NANO:002US.

If the Examiner has any questions, he is invited to contact the undersigned attorney at (512) 536-3116.

Respectfully submitted,



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